Overview

This procedure describes the process for reporting allegations of noncompliance, including noncompliance with Institutional Review Board (IRB) approved protocols, in accordance with University, federal and state requirements for the protection of human research participants.

It is recognized that noncompliance with IRB-approved protocols as well as with established regulations, policies and procedures may also occur during the course of a research study. Some sponsors and investigators refer to such incidents as protocol deviations, while others refer to such events as noncompliance. The Yale IRBs consider all instances of protocol deviations as instances of noncompliance with the approved protocol and handles all protocol deviations as such.

Where to Report

Reports and allegations of serious and/or continuing noncompliance must be reported to the IRB office within five (5) working days of becoming aware of the incident/issue. In general, allegations of noncompliance should be reported to the Human Research Protection Program (HRPP) Compliance Manager or designee at 203-785-4688 or HRPP@yale.edu. Minor noncompliance should be summarized for the IRB at the time of continuing review.

Reports of noncompliance involving the conduct of any of the IRBs or their staff should be reported to the HRPP Compliance Manager or designee (203-785-4688, HRPP@yale.edu) or the Institutional Signatory Official (Associate Vice President for Research Administration, 203-785-3012).

Format and Content of Reports

Allegations of noncompliance are best submitted in writing using Form 700 FR1 (Notification of Deviation from a Protocol/Noncompliance Report Form). However, they may also be submitted via email or presented verbally to the IRB.

Reports should include, to the extent possible:

- The study title, protocol number, and name of the Principal Investigator (PI).
- A description of the event, or the sequence of events that led to the potential noncompliance and the reason why the event(s) is(are) considered noncompliance. (Example: indicate the procedures as outlined in the approved protocol to support the report of an incident of noncompliance.)
- An assessment of why the event occurred or may have occurred.
- An assessment of whether the event adversely affected the rights or welfare of research participants, resulted in harm or posed a significant risk of substantive harm to a research participant or resulted in a detrimental change to a research participant’s clinical or emotional condition/status.
- An assessment of whether the event compromises the integrity or validity of the study data.
- An assessment of whether the incident or deviation occurred due to the willful or knowing misconduct of the PI or study staff.
• A description of any changes to the protocol that will be made as a result of the event.
• A description of any corrective actions that can be, or have been implemented to ensure that similar events do not occur in the future.
• The name of the individual reporting the event. Note that the name of the individual reporting an allegation of noncompliance will be maintained confidentially by the IRB to the fullest extent practicable (see IRB Procedure 700 PR.3 Review and Investigation of Reports of Noncompliance).

Examples of Noncompliance

All instances of protocol deviations are by definition an instance of noncompliance with the approved protocol. The term noncompliance, however, also includes violations of IRB or University policies and procedures, or violations of federal regulations and state statute. Any difference between the IRB approved protocol and the actual activities performed during the conduct of research constitutes noncompliance.

Examples of reportable noncompliance include:

• Failure to obtain prior informed consent from participants (i.e., there is no documentation of informed consent).
• Conducting non-exempt research that requires direct interaction or interventions with human subjects without first obtaining IRB approval.
• Enrolling subjects who fail to meet the inclusion or exclusion criteria in a protocol that involves greater than minimal risk and that in the opinion of the IRB Chair, designee, or convened Committee, places the participant(s) at greater risk.
• Performing a study procedure not approved by the IRB or failing to perform a required study visit or procedure that, in either case, may affect subject safety or data integrity.
• Failing to follow the safety monitoring plan.
• Failing to report serious adverse events and/or unanticipated problems involving risks to subjects or others to the IRB in accordance with IRB Policy 710.
• Protocol deviations that place, or have the potential to place, participants and others at increased risk from the research.
• Enrolling subjects in a study after IRB-approval of that study has expired.
• Failing to submit a continuing review application to the IRB before study expiration.

Revision History

10/12/2009, 10/23/2012